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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,958	09/24/2003	Mark Alan Heldreth	265280-73424	4779

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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,958

Applicant(s)

HELDRETH, MARK ALAN

Examiner

D. Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 and 19-31 are rejected under 35 USC 102(b) as being anticipated by U.S. Publication No.2002/0077542 to Vilsmeier et al. Vilsmeier discloses a system and method for an "orthopaedic" procedure. The method determines the position of "burr," generates a visual or audio cue, and adjusts operation of the surgical burr by adjusting the burr location (paragraphs 14 and 29). Inherently, by locating the position of the surgical burr, the position is located relative to an anatomical feature or any boundary thereabouts.

As the position of the burr is adjusted by the output signal the burr will occasionally pass through bone of different densities. The burr speed will increase or decrease as a result of having moved to bone of a different density (see U.S. Patent No. 4,723,911 to Kurtz).

The system comprises a surgical navigation system. Inherently, a processor is coupled to the surgical burr in order to make adjustments thereto. Inherently, the processor also is coupled to the navigation system in order to determine the relative location of the burr. Inherently, a memory device must be coupled to the processor to

determine the relative position of the burr, adjust operation of the surgical burr and generate a cue to the user.

The system further comprises a controller and a monitor 16.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti. Bonutti discloses a method of operating a surgical burr (the burr is indicated in col. 7, lines 52-53). The user performs the method, rather than a hardware system. To explain this further, a surgeon determines the position of the burr by sight. The brain sends an electronic signal to the hand in response to the determined position to adjust the position of the burr as needed.

Bonutti falls short of disclosing that the burr speed may be adjusted in response to the output signal. Nevertheless, col. 2, lines 44-46 disclose that the drill/burr requires a different speed when cutting through different tissue. When a surgeon passes the drill from one type of tissue to another, a burr speed adjustment would be helpful if not required. For example, it would be helpful to change the burr speed when passing from cortical to cancellous bone, which would more efficiently be done "on the fly," rather than removing the drill, changing the drill speed and replacing the drill. After all, dental

drills are known to change speed as such. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the speed of the drill when passing from one tissue to another in order to quickly accommodate the different tissue.

The tissue border or anatomical feature, acts as a boundary signaling to the using that a modulation in drill speed is necessary. It would have been obvious to one of ordinary skill in the art to either increase or decrease the drill speed as required by the predetermined boundary tissue in order to accommodate the change in tissue.

Response to Arguments

Applicant's arguments filed October 12, 2004 have been fully considered but they are not entirely persuasive.

Applicants state, "There is no teaching in Shahidi of the step of 'adjusting operation of the surgical burr in response to generation of the electric output signal' in response to 'determining position of the surgical burr.'"

The first lines of the Abstract state that the invention is a "method for adjusting the orientation of a surgical viewing instrument." Since the instrument includes a drill/burr (paragraph 28), the invention is also a method for adjusting the orientation of a surgical drill/burr. Moreover, paragraphs 38 and 40 describe tracking the image-guided instrument with respect to markers. Fig. 4 states that a correction is made by a robot in response to an off-set trajectory. For this to occur, the instrument position must be determined and an output signal must be sent to the robot in response to the

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determined position. A controller must then adjust the position as needed. However, the Shahidi reference fails to disclose both "generating a cue" and "adjusting operation of the surgical burr." Therefore, the rejections over Shahidi are rescinded.


The method required by claim 1 is broad enough to include steps performed mentally to manipulate the Bonutti device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (571) 272-4693. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD


GLENN K. DAWSON
PRIMARY EXAMINER